



# **Horizon Europe Programme**

IHI JU Application Form Full proposal (RIA and IA)

**Project proposal – Technical description (Part B)** 

Version 3.0 15 June 2023

## Structure of the Proposal

The proposal contains two parts:

- Part A of the proposal is generated by the IT system. It is based on the information entered by the participants through the submission system in the Funding & Tenders Portal. The participants can update the information in the submission system at any time before final submission.
- Part B of the proposal is the narrative part that includes three sections that each correspond to an evaluation criterion. Part B needs to be uploaded as a PDF document following the templates downloaded by the applicants in the submission system for the specific call or topic. The templates for a specific call may slightly differ from the example provided in this document.

Note: The Horizon Europe Proposal Template Part B has been adapted to reflect the IHI JU specificities.

The electronic submission system is an online wizard that guides you step-by-step through the preparation of your proposal. The submission process consists of 6 steps:

- Step 1: Logging in the Portal
- Step 2: Select the call, topic and type of action in the Portal
- Step 3: Create a draft proposal: Title, acronym, summary, main organisation and contact details
- Step 4: Manage your parties and contact details: add your partner organisations and contact details.
- Step 5: Edit and complete web forms for proposal part A and upload proposal part B
- Step 6: Submit the proposal

	HISTORY OF CHANGES				
Version	on Publication Changes				
1.0	01.06.2022	Initial version			
2.0	01.12.2022	Added instructions on Artificial intelligence so to comply with updated corporate HE RIA full proposals template			
3.0	15.06.2023	Minor changes			
3.0 15.06.2023 Wilnor changes					



# **Proposal template Part B: technical description**

(for full proposals: single stage submission procedure and 2<sup>nd</sup> stage of a two-stage submission procedure)

This template is to be used in a single-stage submission procedure or at the 2<sup>nd</sup> stage of a two-stage submission procedure.

The structure of this template must be followed when preparing your proposal. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the experts to make an effective assessment against the evaluation criteria. Sections 1, 2 and 3 each correspond to an evaluation criterion.

Please be aware that proposals will be evaluated as they were submitted, rather than on their potential if certain changes were to be made. This means that only proposals that successfully address all the required aspects will have a chance of being funded. There will be no possibility for significant changes to content, budget and consortium composition during grant preparation.

Page limit: The title, list of participants and sections 1, 2 and 3, together, should not be longer than 50 pages. All tables, figures, references and any other element pertaining to these sections must be included as an integral part of these sections and are thus counted against this page limit. The number of pages included in each section of this template is only **indicative**.

The page limit will be applied automatically. At the end of this document you can see the structure of the actual proposal that you need to submit, please remove all instruction pages that are watermarked.

If you attempt to upload a proposal longer than the specified limit before the deadline, you will receive an automatic warning and will be advised to shorten and re-upload the proposal. After the deadline, excess pages (in over-long proposals/applications) will be automatically made invisible, and will not be taken into consideration by the experts. The proposal is a self-contained document. Experts will be instructed to ignore hyperlinks to information that is specifically designed to expand the proposal, thus circumventing the page limit.

Please, do not consider the page limit as a target! It is in your interest to keep your text as concise as possible, since experts rarely view unnecessarily long proposals in a positive light.

1 The following formatting conditions apply.

The reference font for the body text of proposals is Times New Roman (Windows platforms), Times/Times New Roman (Apple platforms) or Nimbus Roman No. 9 L (Linux distributions).

The use of a different font for the body text is not advised and is subject to the cumulative conditions that the font is legible and that its use does not significantly shorten the representation of the proposal in number of pages compared to using the reference font (for example with a view to bypass the page limit).

The minimum font size allowed is 11 points. Standard character spacing and a minimum of single line spacing is to be used. This applies to the body text, including text in tables.

Text elements other than the body text, such as headers, foot/end notes, captions, formula's, may deviate, but must be legible.

The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).

	DEFINITIONS
Critical risk	A critical risk is a plausible event or issue that could have a high adverse impact on the ability of the project to achieve its objectives.
	Level of likelihood to occur (Low/medium/high): The likelihood is the estimated probability that the risk will materialise even after taking account of the mitigating measures put in place.
	Level of severity (Low/medium/high): The relative seriousness of the risk and the significance of its effect.
Deliverable	A report that is sent to the Commission or Agency providing information to ensure effective monitoring of the project. There are different types of deliverables (e.g. a report on specific activities or results, data management plans, ethics or security requirements).
Impacts	Wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments (long term). It refers to the specific contribution of the project to the work programme expected impacts described in the topic text. Impacts generally occur some time after the end of the project.
Milestone	Control points in the project that help to chart progress. Milestones may correspond to the achievement of a key result, allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems have arisen, corrective measures can be taken. A milestone may be a critical decision point in the project where, for example, the consortium must decide which of several technologies to adopt for further development. The achievement of a milestone should be verifiable.
Objectives	The goals of the work performed within the project, in terms of its research and innovation content. This will be translated into the project's results. These may range from tackling specific research questions, demonstrating the feasibility of an innovation, sharing knowledge among stakeholders on specific issues. The nature of the objectives will depend on the type of action, and the scope of the topic.
Outcomes	The expected effects, over the medium term, of projects supported under given topic. The results of a project should contribute to these outcomes (described in the topic text), fostered in particular by the dissemination and exploitation measures. This may include the uptake, diffusion, deployment, and/or use of the project's results by direct target groups. Outcomes generally occur during or shortly after the end of the project.
Pathway to impact	Logical steps towards the achievement of the expected impacts of the project over time, in particular beyond the duration of a project. A patiny ay begins with the projects' results, to their dissemination, exploitation and communication, contributing to the expected outcomes in the work programme topic, and ultimately to the wider cientific, economic and societal impacts of the JU's work programme.
Research output	Results generated by the action to vinich access can be given in the form of scientific publications, data or other engineered outcomes and processes such as software, algorithms, protocols and electronic notebooks.
Results	What is generated during the project implementation. This may include, for example, know-how, innovative solutions, algorithms, proof of feasibility, new business models, policy recommendations, guidelines, prototypes, demonstrators, databases and datasets, trained researchers, new intrastructures, networks, etc. Most project results (inventions, scientific works, etc.) are 'Intellectual Property', which may, if appropriate, be protected by formal 'Intellectual

	Property Rights'.
Technology Readiness Level	See Work Programme General Annexes B
In-kind contributions to operational activities (IKOP)	Contributions by IHI private members, their constituent and affiliated entities if any, and by contributing partners, consisting of the eligible costs incurred by them in implementing the IHI projects.
Non-EU IKOP *Only IKOP can be non- EU	Costs for IKOP incurred outside of the EU Member States and countries associated with Horizon Europe provided by private members, their constituent, or the affiliated entities and by contributing partners.  Non-EU contribution shall not exceed 20 % of the overall IKOP at Programme level. In justified cases the IHI JU work programme may set out specific limits for IKOP incurred in third countries, other than countries associated with Horizon Europe.
In-kind contributions to additional activities (IKAA)	Contributions incurred by IHI JU private members, their constituent or affiliated entities, consisting of costs for implementing additional activities less any contribution to those costs from the Union or the IHI JU.  Only IHI private members may report IKAA. Contributing partners cannot report IKAA. They may only contribute IKOP and FC.  IKAA consists of additional activities carried out in the Union or in countries associated with Horizon Europe.  IKAA can be:  Programme specific: additional activities contributing to the uptake of results from IHI JU, IMI2 JU, IMI JU projects or that have a significant added value for the Union.
	Project specific: additional activities contributing towards the achievement of objectives of IHI JU funded projects, or the dissemination, sustainability or exploitation of IHI JU project results, but are not project tasks (i.e. not IKOP).
Financial Contribution (FC)	Financial Contributions (cash contributions) by private members, their constituent or affiliated entities to:  • the JU directly; or
	<ul> <li>project beneficiary(ies) supporting the eligible costs incurred in implementing the IHI projects.</li> </ul>
	Contributing Partners' financial contributions are made only to operational activities.
	Project beneficiaries that are recipients of FC must be eligible for JU funding.

## TITLE OF THE PROPOSAL

1 The consortium members are listed in part A of the proposal (application forms). A summary list should also be provided in the table below.

# **List of participants** [e.g. 1 page]

Participant No. *	Participant organisation short name	Country
1 (Coordinator)		Q
2		
3		

<sup>\*</sup> Please use the same participant numbering and name as that used in the administrative proposal forms.

#### 1. Excellence

#### Excellence – aspects to be taken into account.

- Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
- Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices including sharing and management of research outputs and engagement of citizens, ci ii! society and end users where appropriate.
- The following aspects will be taken into account only to the extent that the proposed work is within the scope of the topic in the work programme.

#### **1.1** Objectives and ambition [e.g. 4 pages]

- Briefly describe the objectives of your proposed work. Explain how they are pertinent to and address all of the objectives listed in the topic text. Are they measurable and verifiable. Are they realistically achievable?
- Describe how your project goes beyond the state-of-the-art, and the extent the proposed work is ambitious. Indicate any exceptional ground-breaking R&I, novel concepts and approaches, new products, services or business and organisational models. Where rale and, illustrate the advance by referring to products and services already available on the mark it Refer to any patent or publication search carried out.
- Describe where the proposed work is positioned in terms of R&I maturity (i.e. where it is situated in the spectrum from 'idea to application', or from 'lab to market'). Where applicable, provide an indication of the Technology Readiness Level, if poss blooding tinguishing the start and by the end of the project.
  - Please bear in mind that advances beyond the state of the art must be interpreted in the light of the positioning of the project. Expectations will not be the same for RIAs at lower TRL, compared with Innovation Actions at high Tables.

# **1.2** Methodology [e.g. 16 nages]

- Describe and explain the overall methodology, including the concepts, models and assumptions that underpin your vork. Explain how this will enable you to deliver your project's objectives. Refer to any important challenges you may have identified in the chosen methodology and how you intend to overcome them. [e.z. 1) pages]
  - 1), is section should be presented as a narrative. The detailed tasks and work packages are described 2 low under 'Implementation'.
  - Where relevant, include how the project methodology complies with the 'do no significant harm'
    principle as per Article 17 of <u>Regulation (EU) No 2020/852</u> on the establishment of a framework to
    facilitate sustainable investment (i.e. the so-called 'EU Taxonomy Regulation'). This means that the
    methodology is designed in a way it is not significantly harming any of the six environmental objectives
    of the EU Taxonomy Regulation.
  - If you plan to use, develop and/or deploy artificial intelligence (AI) based systems and/or techniques you must demonstrate their technical robustness. AI-based systems or techniques should be, or be developed to become:
    - technically robust, accurate and reproducible, and able to deal with and inform about possible failures, inaccuracies and errors, proportionate to the assessed risk they pose

- socially robust, in that they duly consider the context and environment in which they operate
- reliable and function as intended, minimizing unintentional and unexpected harm, preventing unacceptable harm and safeguarding the physical and mental integrity of humans
- able to provide a suitable explanation of their decision-making processes, whenever they can have a significant impact on people's lives.
- Describe any national or international research and innovation activities whose results will feed into the project, and how that link will be established; [e.g. 1 page]
- Explain how knowledge and methods from different disciplines will be brought together and integrated in pursuit of your objectives. In particular, explain how expertise of relevant industry sectors and other healthcare stakeholders are integrated. [e.g. 1 page]
- As relevant, describe the approach to engage with regulatory authorities to nsule translation of results into regulatory practice. Similarly, where relevant, describe the approach to increact with health technology assessment bodies and/or payers [e.g. 1/2 page]
  - The detailed tasks, timelines resources should be considered in a "implementation".
- As relevant, describe how patients, learned societies and heathcare providers' perspectives are incorporated into the proposed methodology [e.g. 1/2 pc ge]
  - The detailed tasks, timelines resources should be considered under "implementation".
- For topics that indicate the need for the integration of social sciences and humanities, show the role of these disciplines in the project or provide a just fication if you consider that these disciplines are not relevant to your proposed project. [e.g. 1/2 p. ge]
- Describe how the gender dimension (i.e. sex and/or gender analysis) is taken into account in the project's research and innovation content [2.g. 1 page]. If you do not consider such a gender dimension to be relevant in your project, pleate provide a justification.\_
  - Note: This section s mandatory except for topics which have been identified in the work programme as not requiring the integration of the gender dimension into R&I content
  - Remember that that this question relates to the <u>content</u> of the planned research and innovation activities, and not to gender balance in the teams in charge of carrying out the project.
  - Sex and gender analysis refers to biological characteristics and social/cultural factors respectively. For goidance on methods of sex / gender analysis and the issues to be taken into account, please refer to https://ec.europa.eu/info/news/gendered-innovations-2-2020-nov-24\_en\_
- Describe how appropriate open science practices are implemented as an integral part of the proposed methodology. Show how the choice of practices and their implementation are adapted to the nature of your work, in a way that will increase the chances of the project delivering on its objectives [e.g. 1 page]. If you believe that none of these practices are appropriate for your project, please provide a justification here.
- Open science is an approach based on open cooperative work and systematic sharing of knowledge and tools as early and widely as possible in the process. Open science practices include early and open sharing

<sup>&</sup>lt;sup>1</sup> Industry sectors: medical imaging, radiotherapy, health ICT and electromedical industries, pharmaceutical industry and vaccine industry, biotechnology industry, medical technology industry.

<sup>&</sup>lt;sup>2</sup> Healthcare stakeholders include patients, carers, health care providers, health care professionals, industry, HTA bodies, regulators, policy makers and payers

of research (for example through preregistration, registered reports, pre-prints, or crowd-sourcing); research output management; measures to ensure reproducibility of research outputs; providing open access to research outputs (such as publications, data, software, models, algorithms, and workflows); participation in open peer-review; and involving all relevant knowledge actors including citizens, civil society and end users in the co-creation of R&I agendas and contents (such as citizen science).

- Please note that this question does not refer to outreach actions that may be planned as part of communication, dissemination and exploitation activities. These aspects should instead be described below under 'Impact'.
- Research data management and management of other research output: Applicants accessing/generating/collecting data and/or other research outputs (except for publications) during the project must provide information how the data/ research outputs will be managed in line with the FAIR principles (Findable, Accessible, Interoperable, Reusable), addressing the following the description should be specific to your project): [e.g. 1,5 pages]

**Types of data/research outputs** (e.g. experimental, observational in 197.s, text, numerical) and their estimated size; if applicable, combination with, and provenance or, existing data.

Access to existing data: Where existing data is to be accessed during the project, the consortium must demonstrate that it has/will have timely access to these uat a.

**Findability of data/research outputs:** Types of prosistent and unique identifiers (e.g. digital object identifiers) and trusted repositories that will be used.

Accessibility of data/research outputs: In Reconsiderations and timeline for open access (if open access not provided, explain why); provisions for access to restricted data for verification purposes.

**Interoperability of data/researc. occputs:** Which standards, formats and vocabularies for data and metadata will be used.

Reusability of dat. / es. arch outputs: Which licenses for data sharing and re-use (e.g. Creative Commons, Open Data Commons) will be used; availability of tools/software/models for data generation and vulidation/interpretation / re-use.

**Curation** and storage/preservation costs; person/team responsible for data management and quality assurance and long-term storage.

- F  $o_F$  os as selected for funding under Horizon Europe will need to develop a detailed data management  $o_F$  in (DMP) for making their data/research outputs findable, accessible, interoperable and reusable (FAIR) as a deliverable by month 6 and revised during the implementation of a project's lifetime.
- Consider including a table to present the information related to data.
- For guidance on open science practices and research data management, please refer to the relevant section of the <u>HE Programme Guide</u> on the Funding & Tenders Portal.

#### 2. Impact

#### Impact – aspects to be taken into account.

- Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.
- Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

The results of your project should make a contribution to the expected outcomes set out for the work programme topic over the medium term, and to the wider expected impacts of the JU over the longer term.

In this section you should show how your project could contribute to the outcomes and impacts described in the work programme, the likely scale and significance of this contribution, and the measures to maximise these impacts.

#### **2.1** Project's pathways towards impact [e.g. 5 pages]

- Provide a narrative explaining how the project's results are expected to make a difference in terms of
  impact, beyond the immediate scope and duration of the project. The narrative should include the
  components below, tailored to your project.
  - (a) Describe the unique contribution your project results would make towards (1) all of the **outcomes** specified in this topic, and (2) the **wider impacts**, in the longer term, aligned with the topic text. Outline the relevant target groups that would benefit from your results and explain how you intend to engage with each of them.
  - Be specific, referring to the effects of your project, and not R&I in general in this field.
  - The outcomes and impacts of your project may:
    - Scientific, e.g. contributing to specific scientific advances, across and within disciplines, creating new knowledge, reinforcing scientific equipment and instruments, computing systems (i.e. research infrastructures);
    - Economic/technological, e.g. bringing new products, services, business processes to the market, increasing efficiency, decreasing costs, increasing profits, contributing to standards' setting, etc.
    - Societal, e.g. decreasing  $CO_2$  emissions, decreasing avoidable mortality, improving policies and decision making, raising consumer awareness.

Only include such outcomes and impacts where your project would make a significant and direct contribution. Avoid describing very tenuous links to wider impacts. However, include any potential negative environmental outcome or impact of the project including when expected results are brought at scale (such as at commercial level). Where relevant, explain how the potential harm can be managed.

- (b) Give an indication of the scale and significance of the project's contribution to the expected outcomes and impacts, should the project be successful. Provide quantified and meaningful estimates where possible, explaining your assumptions.
  - 'Scale' refers to how widespread the outcomes and impacts are likely to be. For example, in terms of the size of the target group, or the proportion of that group, that should benefit over time;

'Significance' refers to the importance, or value, of those benefits. For example, number of additional healthy life years; efficiency savings in energy supply.

- Explain your baselines, benchmarks and assumptions used for those estimates. Wherever possible, quantify your estimation of the effects that you expect from your project. Explain assumptions that you make, referring for example to any relevant studies or statistics. Where appropriate, try to use only one methodology for calculating your estimates: not different methodologies for each partner, region or country (the extrapolation should preferably be prepared by one partner).
- Your estimate must relate to this project only the effect of other initiatives should not be taken into account.
- (c) Describe any requirements and potential barriers arising from factors beyond the scope and duration of the project - that may determine whether the desired outcomes and impacts are achieved. These may include, for example, other R&I work within and beyond Horizon Europe, regulatory environment; targeted markets; user behaviour. Indicate if these factors might evolve over time. Describe any mitigating measures you propose, within or beyond your project, that could be needed should your assumptions prove to be wrong, or to address identified barriers.
  - Note that this does not include the critical risks inherent to the management of the project itself, which should be described below under 'Implementation'
- 2.2 Measures to maximise impact - Dissemination, exploitation and communication [e.g. 5 pages, including section 2.3]
  - Describe the planned measures to maximise the modest of your project by providing a first version of your 'plan for the dissemination and exploitation including communication activities' and where required by the call conditions, include a strategy to ensure affordability, availability and accessibility of products and services based, or partly based, on project results for a period of up to 4 years after the Action<sup>3</sup>. Describe the dissemination, exploitation and communication measures that are planned, and the target group(s) addressed (e.g. scientific community, end users, financial actors, public at large).
    - Please remember that trus plan is an admissibility condition, unless the work programme topic explicitly states of rivise. In case your proposal is selected for funding, a more detailed 'plan for dissemination and exploitation including communication activities' will need to be provided as a mandato. v pr. ject deliverable within 6 months after signature date. This plan shall be periodically update I in augnment with the project's progress.
    - Where required by the call conditions, the 'plan for dissemination and exploitation including communication activities' should include a detailed description of the strategy towards a،fordability, availability and accessibility. The strategy should be updated periodically in alignment with the project's progress and those applicable call conditions.
    - Communication<sup>4</sup> measures should promote the project throughout the full lifespan of the project. The aim is to inform and reach out to society and show the activities performed, and the use and the benefits the project will have for citizens. Activities must be strategically planned, with clear objectives, start at the outset and continue through the lifetime of the project. The description of the communication activities needs to state the main messages as well as the tools and channels that will be used to reach out to each of the chosen target groups.
    - All measures should be proportionate to the scale of the project, and should contain concrete actions to be implemented both during and after the end of the project, e.g. standardisation

<sup>3.</sup> See IHI Guide for Applicants relevant section on 3A "Affordability, availability and accessibility of results".

<sup>&</sup>lt;sup>4</sup> For further guidance on communicating EU research and innovation for project participants, please refer to the Online Manual on the Funding & Tenders Portal<sub>1</sub>

activities. Your plan should give due consideration to the possible follow-up of your project once it is finished. In the justification, explain why each measure chosen is best suited to reach the target group addressed. Where relevant, and for innovation actions, in particular, describe the measures for a plausible path to commercialise the innovations.

- If exploitation is expected primarily in non-associated third countries, justify by explaining how that exploitation is still in the Union's interest.
- Describe possible feedback to policy measures generated by the project that will contribute to designing, monitoring, reviewing and rectifying (if necessary) existing policy and programmatic measures or shaping and supporting the implementation of new policy initiatives and decisions.
- Outline your strategy for the management of intellectual property, foreseen protection measures such as patents, design rights, copyright, trade secrets, etc., and how these would be used to support 'xplication.
  - If your project is selected, you will need an appropriate consortium agreement to manage (amongst other things) the ownership and access to key knowledge (IPR, research date, etc.). Where relevant, these will allow you, collectively and individually, to pursue market opportunities arising from the project.
  - If your project is selected, you must indicate the owner(s) of the results (results ownership list) in the final periodic report.

#### 2.3 Summary

Provide a summary of this section by presenting in the canvas below the key elements of your project impact pathway and of the measures to maximise its impact.

#### **KEY ELEMENT OF THE IMPACT SECTION**

#### **SPECIFIC NEEDS**

What are the specific needs that triggered this project?

#### Example 1

Health solutions need to be better tailored to patients' needs.

Novel approaches are needed to capture patients' needs and to involve them in the development a novel health technology.

#### Example 2

Electronic components need to get smaller and lighter to match the expectations of the end-users. At the same time there is a problem of sourcing of raw materials that has an environmental impact.

#### **EXPECTED RESULTS**

What do you expect to generate by the end of the project?

#### Example 1

Patient-centric clinical development:

Patients perspectives included in design of studies.

Patients' perspective incorporated into the evidence generated for decision making.

## Example 2

Publication of a scientific discovery on transparent electronics.

**New product:** More sustainable electronic circuits.

Three PhD students trained.

#### **D & E & C MEASURES**

What dissemination, exploitation and communication measures will you apply to the results?

#### Example 1

**Exploitation:** Approach to include patients' perspectives is adopted by industry in their novel health technologies development programmes.

**Dissemination towards the scientific community and industry:** Scientific publication of the results of the demonstration pilot

**Communication towards citizens:** An event in a shopping mall to show how the outcomes of the action are relevant to our everyday lives.

## Example 2

**Exploitation of the new product:** Patenting the new product; Licencing to major electronic companies.

Dissemination towards the scientific community and industry:

Participating at conferences; Developing a platform of material compositions for industry; Participation at EC project portfolios to disseminate the results as part of a group and maximise the visibility vis-àvis companies.

#### **TARGET GROUPS**

Who will use or further up-take the results of the project? Who will benefit from the results of the project?

#### Example 1

#### **Healthcare industry companies:**

pharmaceutical (including vaccine), biopharmaceutical, medical (and digital) technologies, etc.

**Scientific community** (clinical research investigations, and testing activities of health solutions)

**End-user of the novel health technology:** patients and citizens

#### Example 2

**End-users**: consumers of electronic devices.

**Major electronic companies**: Samsung, Apple, etc.

**Scientific community** (field of transparent electronics).

#### **OUTCOMES**

What change do you expect to see after successful dissemination and exploitation of project results to the target group(s)?

#### Example 1

**Healthcare industry partners:** novel health technologies adapted to patients' needs.

Use of the scientific results published (measured through the bibliometric indicators of the project publication).

## Example 2

**High use of the scientific discovery published** (measured with the relative rate of citation index of project publications).

A major electronic company (Samsung or Apple) exploits/uses the new product in their manufacturing.

#### **IMPACTS**

What are the expected wider scientific, economic and societal effects of the project contributing to the expected impacts outlined in the topic text?

#### Example 1

**Scientific:** New approach to patient engagement in the development of novel health technologies tailored to the patient's needs.

**Economic/Technological:** Health solutions designed with the patients in mind will facilitate the adoption of the health technology by the market / healthcare system

**Societal:** Patients will benefit from truly patient-centric health technologies (designed from the start based on their needs)

#### Example 2

**Scientific:** New breakthrough scientific discovery on transparent electronics.

**Economic/Technological:** A new market for touch enabled electronic devices.

**Societal:** Lower climate impact of electronics manufacturing (including through material sourcing and waste management).

#### 3. Quality and efficiency of the implementation

#### Quality and efficiency of the implementation – aspects to be taken into account

- Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
- Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.

# **3.1** Work plan and resources [e.g. 17 pages – including tables]

Please provide the following:

- brief presentation of the overall structure of the work plan;
- timing of the different work packages and their components, including a graphic presentation (Gantt chart or similar);
- graphical presentation of overall structure of the work plan showing how the different work packages interrelate (Pert chart or similar).
- detailed work description, i.e.:
  - o a list of work packages (table 3.1a);
  - o a description of each work package (table 3.1b)
    - NOTE: For clinical studies, ensure the information provided under this section is consistent with the information in the Essential Information for Clinical Studies in Horizon Europe Annex (provided in the submission environment)
  - o a list of deliverables (table 3.1c);
    - Give full details. Base your account on the logical structure of the project and the stages in which it is to be carried out. The number of work packages should be proportionate to the scale and complexity of the project.
      - You should give enough detail in each work package to justify the proposed resources to be allocated and also quantified information so that progress can be monitored, including by the Commission.
    - Resources assigned to work packages should be in line with their objectives and deliverables. You are advised to include a distinct work package on 'project management', and a distinct work package on 'dissemination, exploitation and communication activities'.
       Also, give due visibility in the work plan to 'data management', either with distinct tasks or distinct work packages.
    - You will be required to include a 'plan for the dissemination and exploitation of results including communication activities', as a distinct deliverable within the first 6 months of the project. This plan should be updated during the project lifetime, as relevant. This plan should include a record of activities related to dissemination and exploitation that have been undertaken and those still planned.

- You will be required to include a data management plan (DMP) as a distinct deliverable within the first 6 months of the project and revised. This plan should be updated during the project lifetime, as relevant.
- If relevant, and as indicated in the Essential Information for Clinical Studies in Horizon Europe Annex (available in the submission environment), the three mandatory deliverables applicable to each clinical study must be included in the proposal.
- Please make sure the information in this section matches the costs as stated in the budget table in section 3 of the application forms, and the number of person months, shown in the detailed work package descriptions.
- a list of milestones (table 3.1d);
- a list of critical risks, relating to project implementation, that the stated project's objectives may not be achieved. Detail any risk mitigation measures. You will be able to update the list of critical risks and mitigation measures as the project progresses (table 3.1e);
- a table showing number of person months required (table 3.1f);
- a table showing description and justification of subcontracting costs for each participant (table 3.1g);
- a table showing justifications for 'purchase costs' (table 3.1h) for participants where those costs exceed 15% of the personnel costs (according to the budget table in proposal part A);
- if applicable, a table showing justifications for 'other costs categories' (table 3.1i);
- if applicable, a table showing in-kind contributions from third parties (table 3.1j);
- if applicable, a table showing the financial contributions from participants which are IHI JU members<sup>5</sup>, contributing partners<sup>6</sup>, or their affiliates or constituent entities (table 3.1k);
- if applicable, a table showing the non-EU in kind contributions to operational activities (IKOP) provided by the participants which are IHI JU members, their affiliates or constituent entities or contributing partners (table 3.1l);
- if applicable, an annex describing the project related in-kind contributions to additional activities (IKAA)<sup>7</sup> (annex available in the submission environment).

## 3.2 Capacity of participants and consortium as a whole [e.g. 3 pages]

⚠ The individual participants of the consortium are described in a separate section under Part A. There is no need to repeat that information here.

Describe the consortium. How does it match the project's objectives, and brings together the necessary
disciplinary and inter-disciplinary knowledge. Show how this includes expertise in social sciences and
humanities, open science practices, and gender aspects of R&I, as appropriate. Include in the description
affiliated entities and associated partners, if any.

<sup>&</sup>lt;sup>5</sup> IHI JU members: The partners of IHI are the European Union, represented by the European Commission, and the European life science industry, represented by the industry associations COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe

<sup>&</sup>lt;sup>6</sup> Contributing partners: health stakeholders who may want to invest in IHI without becoming full members. Contributing partners invest their own resources or cash in a specific IHI project or projects. Their contributions work in a similar way to contributions by industry partners.

<sup>&</sup>lt;sup>7</sup> IKAA: Contributions incurred by IHI JU private members, their constituent or affiliated entities, consisting of costs for implementing additional activities less any contribution to those costs from the Union or the IHI JU.

- Show how the partners will have access to critical infrastructure needed to carry out the project activities.
- Describe how the participants complement one another (and cover the value chain, where appropriate) and create a successful public private partnership.
- In what way does each of the participants contribute to the project? Show that each of them (including those which are IHI JU members contributing partners) has a valid role, and adequate resources in the project to fulfil that role.
- Other countries and international organisations: If one or more of the participants requesting TU funding is based in a country or is an international organisation that is not automatically eligible for act funding (entities from Member States of the EU, from Associated Countries and from one of the countries in the exhaustive list included in the Work Programme General Annexes B are automatically eligible for EU funding), explain why the participation of the entity in question is essential to successfully carry out the project.

#### Tables for section 3.1

Less blain text for the tables in section 3.1. If the proposal is invited to start Grant Agreement preparation, these tables will have to be encoded in the grant management IT tool, where no traphics or special formats are supported.

Table 3.1a: List of work packages

Work package No	Work Package Title	Lead Participant No	Lead Pirtisipunt Shart Name	Person- Months	Start Month	End month
		5	1			
	×	10				
	, C					

## Table 3.1b: Work package description

## For each work package:

Work package number	
Work package title	

• Participants involved in each WP and their efforts are shown in table 3.1f. Lead participant and starting and end date of each WP are shown in table 3.1a.)

Objectives
Description of work (where appropriate, broken down into tasks), lead partner and role of participants. Deliverables linked to each WP are listed in table 3.1c (no need to repeat the information here).
· · · · · · · · · · · · · · · · · · ·

#### Table 3.1c: List of Deliverables<sup>8</sup>

Only include deliverables that you consider essential for effective project monitoring.

Numbe r	Deliverable name	Short description <sup>9</sup>	Work packag e numbe r	Short name of lead participan t	Typ e	Dissemi nation level	Delivery date (in months)
							0.

#### **KEY**

Deliverable numbers in order of delivery dates. Please use the numbering convention <WP number>.<number of deliverable within that WP>.

For example, deliverable 4.2 would be the second deliverable from work package 4

# Type:

Use one of the following codes:

R: Document, report (excluding the periodic and final reports)

DEM: Demonstrator, pilot, prototype, plan designs

DEC: Websites, patents filing, press & media actions, videos, etc.

DATA: Data sets, microdata, etc. DMP: Data management plan

ETHICS: Deliverables related to ethics issues.

SECURITY: Deliverables related to security issues

OTHER: Software, technical diagram, algorithms, models, etc.

#### **Dissemination level:**

Use one of the following codes:

PU – Public, fully open, e.g. web (Deliverables flagged as public will be automatically published in

CORDIS project's page)

SEN – Sensitive, limited under the conditions of the Grant Agreement

Classified R-UE/EU-R - EU RESTRICTED under the Commission Decision No2015/444

Classified C-UE/EU-C - EU CONFIDENTIAL under the Commission Decision No2015/444

Classified S-UE/EU-S - EU SECRET under the Commission Decision No2015/444

## **Delivery date**

Measured in months from the project start date (month 1)

You must include a data management plan (DMP) and a 'plan for dissemination and exploitation including communication activities as distinct deliverables within the first 6 months of the project. These plans should be updated during the project lifetime, as relevant. A template for the DMP is available in the Online Manual on the Funding & Tenders Portal. For proposals with clinical studies, the three mandatory clinical study deliverables must be included for each study

<sup>9</sup> Please also include in this section the expected generating applicant for the concerned deliverable

#### Table 3.1d: List of milestones

Milestone number	Milestone name	Related work package(s)	Due date (in month)	Means of verification

#### **KEY**

#### Due date

Measured in months from the project start date (month 1)

#### Means of verification

Show how you will confirm that the milestone has been attained. Refer to indicators if a propriate. For example: a laboratory prototype that is 'up and running'; software released and you do a user group; field survey complete and data quality validated.

#### Table 3.1e: Critical risks for implementation

Description of risk (indicate level of (i)	Work package(s)	Proposed risk-mitigation measures
likelihood, and (ii) severity:	involved	
Low/Medium/High)		
	6	
	77,	

## **Definition critical risk:**

A critical risk is a plausible even or issue that could have a high adverse impact on the ability of the project to achieve its objectives.

# Level of likelihood to ccur: .ow/medium/high

The likelihood is the estimated probability that the risk will materialise even after taking account of the mitigating measures but in place.

## Level of severity: Low/medium/high

The relative soriousness of the risk and the significance of its effect.

## Table 3.1f: Summary of staff effort

Please indicate the number of person/months over the whole duration of the planned work, for each work package, for each participant. Identify the work-package leader for each WP by showing the relevant person-month figure in bold.

	WPn	WPn+1	WPn+2	Total Person- Months per Participant
Participant				
Number/Short Name				
Participant Number/				
Short Name				
Participant Number/				
Short Name				
<b>Total Person Months</b>				

## Table 3.1g: 'Subcontracting costs' items

For each participant describe and justify the tasks to be subcontracted (please note that core task) or the project should not be sub-contracted).

Participant Number/Shor	t Name		
	Cost (€)	Description of tasks and justification	
Subcontracting			0.

#### Table 3.1h: 'Purchase costs' items (travel and subsistence, equipment and other goods, works and services)

Please complete the table below for each participant if the purchas a costa (i.e. the sum of the costs for 'travel and subsistence', 'equipment', and 'other goods, works and servical') exceeds 15% of the personnel costs for that participant (according to the budget table in proposal part A). The record must list cost items in order of costs and starting with the largest cost item, up to the level that the remaining costs are below 15% of personnel costs.

Participant Number/Shor	t Name	<u>,0</u> ,
	Cost (€)	Justification
Travel and subsistence		
Equipment		
Other goods, works and		
services		
Remaining purchase		
costs (<15% of pers.	X	
Costs)		
Tota.		

## Table 3.1i: 'Other costs categories' items (e.g. internally invoiced goods and services)

Please complete the table below for each participant that would like to declare costs under other costs categories (e.g. internally invoiced goods and services), irrespective of the percentage of personnel costs.

Participant Number/Short Name				
	Cost (€)	Justification		
Internally invoiced				
goods and services				
•••				

## Table 3.1j: 'In-kind contributions' provided by third parties

Please complete the table below for each participant that will make use of in-kind contributions (non-financial resources made available free of charge or against payment by third parties). In kind contributions provided by third parties are declared by the participants as eligible direct costs in the corresponding cost category (e.g. personnel costs or purchase costs for equipment).

Participant Number/S	Participant Number/Short Name				
Third party name	Category	Cost (€)	Justification		
	Select between				
	Seconded personnel		0,0		
	Travel and subsistence				
	Equipment		·		
	Other goods, works and				
	services	2)			
	Internally invoiced				
	goods and services				
	.(0)				

## Table 3.1k: Financial contributions<sup>10</sup>

For each financial contribution provided by IHI JU private members, their constituent or affiliated entities, and contributing partners to beneficiaries, please complete the table below.

FC provided by	FC received by	Amount (€)	Related activities
Participant Number/Short Name	Participant Number/Short Name		

#### Table 3.11: Non-EU<sup>11</sup> in-kind contributions to operational activities

For non-EU in kind contributions to operational activities (IKOP) provided by IHI JU private members, their constituent or affiliated entities, and contributing partners please complete the table below. Please consider that

<sup>&</sup>lt;sup>10</sup> Financial transfer (cash contributions) by private members, their constituent or the affiliated entities and by contributing partners to project beneficiary(ies) eligible for funding, supporting the eligible costs incurred in the implementing the IHI project

Costs for IKOP incurred by IHI JU private members, their constituent or affiliated entities, and contributing partners in third countries, i.e. other than EU Member States and countries associated to Horizon Europe

non-EU IKOP in your proposed action is limited to the amount indicated in the relevant IHI JU Annual Work Programme/Topic text. Activities are considered "non-EU" when they are incurred outside the Union or HE's associated countries, irrespectively of the country of establishment of the legal entity providing the IKOP.

Participant	Non-EU activities and justification
Participant	
Number/Short Name	

# Table 3.1m: In-kind contributions to additional activities (IKAA)

nstructions, please ref Please fill in the annex for in-kind contributions to additional activities (IKAA) (provider in the submission environment)

#### ANNEXES TO PROPOSAL PART B

The annexes need to be uploaded as separate documents in the submission system.

#### **Annex: Type of Participants**

The "type of participants" is an IHI specific annex. The excel template can be found <a href="here">here</a> and the instructions on how to fill in this template can be found <a href="here">here</a>.

This is a compulsory annex and it must be uploaded as separate document in the submission system.

#### Annex: Declaration of in-kind contribution commitment.

The 'Declaration of in-kind contribution commitment" is an IHI specific annex.

The word document template can be found here.

This is a is a compulsory annex and it must be uploaded as separate document in the submission system.

Consortia are invited to identify an industry lead for participants providing in-kind contributions. These participants are strongly invited to liaise with their IHI / Horizon Europe contact person within their own organisation to prepare their declaration of in-kind contribution commitment.

#### Annex: In-kind contributions to additional activities (IKAA)

The "In-kind contributions to additional activities (IKAA)" is an IHI specific annex. The excel template can be found <a href="here">here</a> and the instructions on how to fill in this template can be found <a href="here">here</a>.

#### **Annex: Essential information for clinical studies**

This is a HE annex and it is compulsory if the proposal includes clinical studies 12.

Information on clinical studies can be found here.

If your proposal does not include clinical studies, please upload a statement declaring your proposal does not include clinical studies, otherwise you won't be able to submit the proposal.

#### **Annex: Ethics**

This is a HE annex. Ethics self-assessment should be included in proposal part A. However, in calls where several serious ethics issues are expected, the character limited in this section of proposal part A may not be sufficient for participants to give all necessary information. In those cases, participants may include additional information in an annex to proposal part B.

#### Annex: to the budget for the Full Proposal

This is a compulsory <u>annex</u>, which complements the budget figures already included in the proposal budget in PART A. Its purpose is to correctly guide the consortium in providing IHI-specific budget items (e.g. IKOP, IKAA, FC PAID, FC RECEIVED, etc.) and to comply with IHI additional eligibility criteria (e.g. 45% industry contribution).

<sup>&</sup>lt;sup>12</sup> Clinical study means any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

# Proposal template Part B: technical description

# TITLE OF THE PROPOSAL

# List of participants

Participant No. *	Participant organisation name	Country
1 (Coordinator)		
2		
3		

## 1. Excellence

# 1.1 Objectives and ambition

Insert here text for your proposal

# 1.2 Methodology

Insert here text for your proposal

# 2. Impact

# 2.1 Project's pathways towards impact

Insert here text for your proposal

# 2.2 Measures to maximise impact - Dissemination, exploitation and communication

Insert here text for your proposal

# 2.3 Summary

# KEY ELEMENT OF THE IMPACT SECTION

SPECIFIC NEEDS	EXPECTED RESULTS	D & E & C MEASURES
What are the specific needs that triggered this project?	What do you expect to generate by the end of the project?	What dissemination, exploitation and communication measures will you apply to the results?
Insert here text for your proposal	Insert here text for your proposal	Insert here text for your proposal

# **TARGET GROUPS**

Who will use or further up-take the results of the project? Who will benefit from the results of the project?

Insert here text for your proposal

# **OUTCOMES**

What change do you expect to see after successful dissemination and exploitation of project results to the target group(s)?

Insert here text for your proposal

# **IMPACTS**

What are the expected wider scientific, economic and societal effects of the project contributing to the expected impacts outlined in the respective destination in the work programme?

Insert here text for your proposal

# 3. Quality and efficiency of the implementation

# 3.1 Work plan and resources

Insert here text for your proposal

# 3.2 Capacity of participants and consortium as a whole

Insert here text for your proposal

# Tables for section 3.1

# Table 3.1a: List of work packages

Work package No	Work Package Title	Lead Participant No	Lead Participant Short Name	Person- Months	Start Month	End month

# **Table 3.1b:** Work package description

For each work package:

Work package number	
Work package title	
Objectives	
Danish diana afamanla	
Description of work	

# **Table 3.1c:** List of Deliverables

Numbe r	Deliverable name	Short description	Work package number	Short name of lead participant	Туре	Disse minati on level	Delivery date (in months)

# **Table 3.1d:** List of milestones

Milestone number	Milestone name	Related work package(s)	Due date (in month)	Means of verification

# Table 3.1e: Critical risks for implementation

Description of risk (indicate level of (i) likelihood, and (ii) severity: Low/Medium/High)	Work package(s) involved	Proposed risk-mitigation measures

# **Table 3.1f:** Summary of staff effort

	WPn	WPn+1	WPn+2	Total Person- Months per Participant
Participant				
<b>Number/Short Name</b>				
Participant Number/				
Short Name				
Participant Number/				
Short Name				
<b>Total Person Months</b>				

# Table 3.1g: 'Subcontracting costs' items

Participant Number/Short Name			
	Cost (€)	Description of tasks and justification	
Subcontracting			

# Table 3.1h: 'Purchase costs' items (travel and subsistence, equipment and other goods, works and services)

Participant Number/Short Name			
	Cost (€)	Justification	
Travel and subsistence			
Equipment			
Other goods, works			
and services			
Remaining purchase			
costs (<15% of pers.			
Costs)			
Total			

# Table 3.1i: 'Other costs categories' items (e.g. internally invoiced goods and services)

Participant Number/Short Name		
	Cost (€)	Justification
Internally invoiced		
goods and services		
•••		

# Table 3.1j: 'In-kind contributions' provided by third parties

Participant Number/Short Name			
Third party name	Category	Cost (€)	Justification
	Select between		
	Seconded personnel		
	Travel and subsistence		
	Equipment		
	Other goods, works and services		
	Internally invoiced goods and services		

## **Table 3.1k:** Financial contributions

FC provided by	FC received by	Amount (€)	Related activities
Participant	Participant		
Number/Short	Number/Short		
Name	Name		

# Table 3.11: Non-EU in-kind contributions to operational activities

Participant	Non-EU activities and justification
Participant	
Number/Short Name	